

CLAIMS

1. An aerosol preparation, comprising:
an aerosol composition containing a macrolide compound; and
an enclosure enclosing the aerosol composition, the enclosure including a valve part having a "gasket" made of at least one resinous material selected from butyl rubber, ethylene-propylene rubber, chloroprene rubber, polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene, polypropylene and thermoplastic elastomer.
2. The aerosol preparation according to claim 1, wherein the macrolide compound is tacrolimus or hydrated tacrolimus.
3. The aerosol preparation according to claim 2, wherein the content of the tacrolimus or the hydrated tacrolimus in the aerosol composition is not more than 0.15wt%.
4. The aerosol preparation according to any of claims 1 to 3, wherein the aerosol composition further contains a liquefied hydrofluoroalkane.
5. The aerosol preparation according to claim 4, wherein the liquefied hydrofluoroalkane is one of HFA-134a and HFA-227, or a mixture of them.
6. The aerosol preparation according to any of claims 1 to 5, wherein the aerosol composition further contains a medium-chain fatty acid triglyceride.
7. The aerosol preparation according to any of claims 1 to 6, wherein the enclosure is a metered dose inhaler.

8. The aerosol preparation according to any of claims 1 to 7, wherein the “gasket” is made of at least one resinous material selected from butyl rubber, ethylene-propylene rubber, chloroprene rubber and thermoplastic elastomer.

9. The aerosol preparation according to any of claims 1 to 8, wherein the selected at least one resinous material made into the “gasket” is the thermoplastic elastomer, which is at least one rubber selected from a rubber group consisting of butyl rubber, ethylene-propylene rubber and chloroprene rubber, mixed with at least one plastic selected from a plastic group consisting of polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene and polypropylene.

10. The aerosol preparation according to claim 9, wherein the thermoplastic elastomer is a mixture of butyl rubber and polyethylene.

11. The aerosol preparation according to any of claims 1 to 10, wherein the selected at least one resinous material made into the “gasket” has such a characteristic that, just after the resinous material having 39mm² surface area has been soaked in the 10ml aerosol composition having the 0.025wt% macrolide compound for a month under a condition of 75% relative humidity and 40°C, the amount of the remaining macrolide compound in the aerosol composition is not less than 80% of the amount of the initial macrolide compound before the soaking.

12. The aerosol preparation according to any of claims 1 to 10, the “gasket” comprising a neck gasket portion for ensuring airtightness of the enclosure, wherein the neck gasket portion is made of at least one resinous material selected from butyl rubber, ethylene-propylene rubber, chloroprene rubber, polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene, polypropylene and thermoplastic elastomer.

13. The aerosol preparation according to claim 12, wherein the selected at least one resinous material made into the neck gasket portion is the butyl rubber or the thermoplastic elastomer.

14. The aerosol preparation according to claim 13, wherein the thermoplastic elastomer made into the neck gasket portion is at least one rubber selected from a rubber group consisting of butyl rubber, ethylene-propylene rubber and chloroprene rubber, mixed with at least one plastic selected from a plastic group consisting of polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene and polypropylene.

15. The aerosol preparation according to claim 14, wherein the thermoplastic elastomer made into the neck gasket portion is a mixture of butyl rubber and polyethylene.

16. The aerosol preparation according to any of claims 12 to 15, wherein the selected at least one resinous material made into the neck gasket portion has such a characteristic that, just after the resinous material having 39mm^2 surface area has been soaked in the 10ml aerosol composition having the 0.025wt% macrolide compound for a month under a condition of 75% relative humidity and 40°C , the amount of the remaining macrolide compound in the aerosol composition is not less than 80% of the amount of the initial macrolide compound before the soaking.

17. The aerosol preparation according to any of claims 1 to 10, the valve part of the enclosure further comprising:

a metering chamber into which a fixed volume of the aerosol composition is taken out from the inside of the enclosure; and

a slide member, wherein the slide member slides toward the inside of the enclosure so as to bring the metering chamber into communication with an inside of

the enclosure, and wherein the slide member slides outward from the enclosure so as to bring the metering chamber into communication with an outside of the enclosure and to spray out the fixed volume of the aerosol composition from the metering chamber, the "gasket" of the valve part including:

a neck gasket portion for ensuring airtightness of the enclosure;

a first gasket portion contacting the slide member so as to airtightly isolate the inside of the enclosure from the metering chamber; and

a second gasket portion contacting the slide member so as to airtightly isolate the metering chamber from the outside of the enclosure,

wherein each of the neck gasket portion, the first gasket portion and the second gasket portion is made of at least one resinous material selected from butyl rubber, ethylene-propylene rubber, chloroprene rubber, polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene, polypropylene and thermoplastic elastomer.

18. The aerosol preparation according to claim 17, wherein the neck gasket portion is made of thermoplastic elastomer which is at least one rubber selected from a rubber group consisting of butyl rubber, ethylene-propylene rubber and chloroprene rubber, mixed with at least one plastic selected from a plastic group consisting of polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene and polypropylene, and wherein each of the first and second gasket portions is made of butyl rubber, ethylene-propylene rubber or chloroprene rubber.

19. The aerosol preparation according to claim 18, wherein the neck gasket portion is made of thermoplastic elastomer which is a mixture of butyl rubber and polyethylene, and wherein each of the first and second gasket portions is made of chloroprene rubber.

20. The aerosol preparation according to any of claims 17 to 19, wherein the selected at least one resinous material made into each of the neck gasket portion, the first gasket portion and the second gasket portion has such a characteristic that, just after the resinous material having 39mm^2 surface area has been soaked in the 10ml aerosol composition having the 0.025wt% macrolide compound for a month under a condition of 75% relative humidity and 40°C , the amount of the remaining macrolide compound in the aerosol composition is not less than 80% of the amount of the initial macrolide compound before the soaking.

21. The aerosol preparation according to any of claims 1 to 20, the valve part further comprising a metering chamber member, a slide member and a housing, wherein at least one of the metering chamber member, the slide member and the housing is made of at least one resinous material selected from a plastic group including polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene and polypropylene.

22. The aerosol preparation according to claim 21, wherein the at least one of the metering chamber member, the slide member and the housing is made of polybutylene terephthalate.

23. The aerosol preparation according to claim 21 or 22, wherein the at least one of the metering chamber, the slide member and the housing is made of resinous material having such a characteristic that, just after the resinous material having 39mm^2 surface area has been soaked in the 10ml aerosol composition having the 0.025wt% macrolide compound for a month under a condition of 75% relative humidity and 40°C , the amount of the remaining macrolide compound in the aerosol composition is not less than 80% of the amount of the initial macrolide compound before the soaking.

24. The aerosol preparation according to any of claims 1 to 23, the valve part further comprising a protection ring made of at least one resinous material selected from a plastic group including polyethylene, polybutylene terephthalate, polyacetal, polyamide, polytetrafluoroethylene and polypropylene.

25. The aerosol preparation according to claim 24, wherein the protection ring is made of polyethylene or polyamide.

26. The aerosol preparation according to claim 24 or 25, wherein the protection ring is made of resinous material having such a characteristic that, just after the resinous material having 39mm^2 surface area has been soaked in the 10ml aerosol composition having the 0.025wt% macrolide compound for a month under a condition of 75% relative humidity and 40°C , the amount of the remaining macrolide compound in the aerosol composition is not less than 80% of the amount of the initial macrolide compound before the soaking.